

INTERNATIONAL SEARCH REPORT

Intern Application No
PCT/US2004/032064

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|---|-------------------------------|
| X | US 4 506 680 A (STOKES KENNETH B) 26 March 1985 (1985-03-26) | 1, 3-11, 18, 19, 22, 23 |
| A | the whole document | 2, 12-17, 20, 21, 24-35 |
| X | ----- US 2002/077685 A1 (SOMMER JOHN L ET AL) 20 June 2002 (2002-06-20) the whole document | 1 |
| X | ----- EP 0 791 372 A (MEDTRONIC INC) 27 August 1997 (1997-08-27) the whole document | 1 |
| A | ----- US 6 263 249 B1 (STEWART MARK T ET AL) 17 July 2001 (2001-07-17) abstract | 1-35 |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

13 December 2004

Date of mailing of the international search report

21/12/2004

Name and mailing address of the ISA

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Authorized officer

Gaillard, A

INTERNATIONAL SEARCH REPORT

Information on patent family members

 Intern I Application No
 PCT/US2004/032064

| Patent document cited in search report | | Publication date | Patent family member(s) | | Publication date |
|--|----|------------------|-------------------------|------------|------------------|
| US 4506680 | A | 26-03-1985 | NONE | | |
| US 2002077685 | A1 | 20-06-2002 | NONE | | |
| EP 0791372 | A | 27-08-1997 | US 5987746 A | 23-11-1999 | |
| | | | AU 703414 B2 | 25-03-1999 | |
| | | | AU 1473497 A | 28-08-1997 | |
| | | | CA 2197274 A1 | 21-08-1997 | |
| | | | DE 69727329 D1 | 04-03-2004 | |
| | | | DE 69727329 T2 | 21-10-2004 | |
| | | | EP 0791372 A1 | 27-08-1997 | |
| | | | JP 9225041 A | 02-09-1997 | |
| US 6263249 | B1 | 17-07-2001 | US 2001029395 A1 | | 11-10-2001 |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 17 DEC 2004

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US2004/032064

International filing date (day/month/year)
30.09.2004

Priority date (day/month/year)
30.09.2003

International Patent Classification (IPC) or both national classification and IPC
A61N1/05

Applicant
CARDIAC PACEMAKERS, INC.

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/032064

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 in written format
 in computer readable form
 - c. time of filing/furnishing:
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. II Priority

1. The following document has not been furnished:

copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
 translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|-------------|---------------------|
| Novelty (N) | Yes: Claims | 2,12-17,20,21,24-35 |
| | No: Claims | 1,3-11,18,19,22,23 |
| Inventive step (IS) | Yes: Claims | 2,12-17,20,21,24-35 |
| | No: Claims | 1,3-11,18,19,22,23 |
| Industrial applicability (IA) | Yes: Claims | 1-35 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.
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Re Item V.

V.1 The following documents are referred to in this communication:

D1 : US 4 506 680 A (STOKES KENNETH B) 26 March 1985 (1985-03-26)
D2 : US 2002/077685 A1 (SOMMER JOHN L ET AL) 20 June 2002 (2002-06-20)
D3 : EP 0 791 372 A (MEDTRONIC INC) 27 August 1997 (1997-08-27)

V.2 Independent claim 1

The document D1 is regarded as being the closest prior art to the subject-matter of independent device claim 1, and discloses (the references in parentheses applying to this document) an electrical lead comprising a lead conductor and an electrode (22) including a portion coated(34) with two layers having pharmacological agent like dexamethasone.

thus D1 specifies all the features of Claim 1 of the present application. Therefore the present application does not meet the requirement of Article 33(2) PCT because the subject-matter of claim 1 is not novel.

V.3 Dependent claims 3-11, 18, 19, 22, 23

Dependent claims 3-11, 18, 19, 22, 23 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty because said feature are also disclosed in document D1.

Re Item VII.

The attention of the applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

Reference signs of the drawings should be mentioned in the claims to these features.

Documents **D1 should be identified** in the description and the relevant background art disclosed therein should be briefly discussed.

**WRITTEN OPINION OF THE
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Independent claims are not in the **two-part form**, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble and with the remaining features being included in the characterising part.

The dependant claims should be drafted having regard to the new independent claim.